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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,433	03/15/2004	Gregory Murphy	5838-00205	1763

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EXAMINER	
SETH, MANAV	

ART UNIT	PAPER NUMBER
2624	

NOTIFICATION DATE	DELIVERY MODE
07/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/800,433	MURPHY ET AL.	
	Examiner	Art Unit	
	MANAV SETH	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *567-572* is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *518,527,529,530,554,563,565 and 566* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 156,157,495-510,512-514,516-521,523-546,548-550,552-557 and 559-572.

Continuation of Disposition of Claims: Claims rejected are 156,157,495-502,510,512-514,516,517,519-521,523-526,528,531-546,548-550,552,553,555-557,559-562 and 564.

DETAILED ACTION

Response to Amendment

1. The amendment received on April 30, 2009 has been entered in full.

2. Applicant's amendment to the claims has been entered and based on the amendments claim rejections under 35 USC 101 and 112 on the respective claims have been withdrawn.

3. Applicant has added the previously allowed subject matter in the independent claims 156 and 157. This allowed subject matter has been reanalyzed and based on the analysis, the allowance of this subject matter has been withdrawn.

4. Applicant's arguments with respect to amended claims as presented in the amendment filed have been fully considered but are moot in view of new ground(s) of rejection(s).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 156, 157, 495, 496, 531 and 532 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duran et al., U.S. Patent No. 6,491,511, further in view of Bradbury et al. U.S. Patent Publication No. US2002/0007294 A1 and further in view of Halmann et al., U.S. Patent No. 5,151,856.

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Regarding claims 156 and 157, these claims recite two components:

1st component: using first images to create a pattern of at least a portion of at least one patient-specific cardiac instrument or implant using at least one image of heart tissue form a human heart, and

2nd component is using first images to create at least a second image of the heart tissue, wherein at least a portion of the second image appears four-dimensional.

Clearly, there is no connection between these two components except that same first images could be used to perform both components.

Duran discloses "the present invention is in the field of equipment and devices related to manufacturing heart valves to be used in cardiac surgery (col. 1, lines 6-10). Duran further discloses the use of echocardiograms (heart images which includes a heart valve tissues of the heart) data in order to make or construct a custom replacement heart valve (patient specific heart implant/instrument) (col. 6, lines 50-65) but does not expressly provide the details of how such patient specific implant would be created using the heart images data, which details would further include creating a pattern of at least a portion of at least one patient-specific cardiac instrument or implant using at least one image of heart tissue from a human heart. Therefore, examiner cites Bradbury to provide the details of the implant construction. Bradbury discloses "a CPU; and a system memory coupled to the CPU, wherein the system memory stores on or more computer programs executable by the CPU (paragraph 0014 – the use of computer where CPU being an inherently required part of the computer and para 0015 -different memories).

Bradbury further discloses "the present invention is directed to the preparation of rapid-prototyped implantable biomedical devices manufactured using a patient's own diagnostic imaged data" (para. 0013). Bradbury further discloses "the present invention provides a new method of rapid design and manufacture of biomedical implants using electronic data and modeling transmissions. **The method includes the steps of capturing patient anatomical data, converting the data to a computer file, converting the computer file into a multi-dimensional model and then into machine instructions, and finally manufacturing the medical device such as an implant**" (para 0014).

Bradbury further discloses capturing patient anatomical data – "in manufacturing customized implants or devices, the starting point is patient-specific information 100 obtained from various non-invasive or invasive procedures. Non-invasive procedures from which patient data may be obtained include diagnostic or radiological data such as magnetic resonance imaging (MRI) scans, computerized tomography (CT) scans, ultrasounds or nuclear medicine procedures or mammography procedures (para 0016). Bradbury further discloses "Patient data from, for example, **MRI or CT scans is normally presented as sets of two-dimensional images (sections) showing all of the patient's tissues**…..CT scans are considered better for imaging hard tissue such as bone, and MRI scans are considered better for **imaging soft tissue**" (para 0019). Bradbury further discloses "the diagnostic scans may need further processing which may include distinguishing between hard and soft tissue…in the two-dimensional planes or sections in which the MRI or CT scans typically are presented…this initially processed data may further be converted to a form that geometrically represents a multi-dimensional form representing an object…."(para 0020). Bradbury further discloses "Once a multidimensional model has been created from the diagnostic data, the multidimensional model essentially becomes just another data set or mathematical object

capable of being further processed or manipulated by typical CAD software" (para 0022). Bradbury further discloses that the patient specific implant could be designed for **soft tissues** (para 0076, last 2 lines). Thus, from the above citation, **the multidimensional CAD model being the pattern created of at least patient specific instrument or implant using images of the patient tissues**.

Bradbury does not explicitly disclose the image being an image of heart tissue from a human heart, but, as cited before, Bradbury does disclose that the patient specific implant could be designed for soft tissues based on tissue images (para 0076, last 2 lines) and as well known heart is nothing but a structure of soft tissues. Therefore, it would be obvious to one of ordinary skill in the art at the time of invention was made to combine the teachings of Duran and Bradbury to create a pattern of at least one patient-specific cardiac instrument or implant using at least one image of heart tissue from a human heart because both Duran and Bradbury are directed to the same field of constructing a patient specific body implant and directed to the same field of constructing a patient specific body implant and Bradbury provides the details of a method and system which creates a computer model/pattern of the implant according to patient specifics from the tissue images of different parts of the body, thus providing a versatile method and system to provide any kind of computer model/pattern for any kind of human implants, which model would further provide the user with additional manipulation capabilities to improve the geometrical accuracy of the implant, if required, and further adding, such a computer model/pattern could easily be converted into machine instructions to facilitate automated construction of the implant. (see Bradbury – para 0015).

As discussed in the rejection with respect to Duran and Bradbury, the images are be used to develop/create multi-dimensional data in order to analyze heart tissues but both Duran and Bradbury do explicitly teach such a multidimensional data to be a 4 dimensional data. As well known

4-dimensional image is a 3-dimensional image with time dimension added to it so that an animation of 3D image can be provided. It is very well known in the art of medical imaging analysis to create and use 4D images (3D animation) and Halmann teaches the same in (col. 3, lines 50-52; col. 9, lines 15-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to use Halmann's teachings into the combined invention of Duran and Bradbury. One of ordinary skill in the art at the time of invention was made would have been motivated to use Halmann's teachings into the combined invention of Duran and Bradbury because all references are directed to same field of endeavor (medical (heart) analysis) and 4 dimensional images would provide a real time analysis of the heart tissues.

Regarding claims 495 and 531, Bradbury discloses the pattern is created automatically by at least one of the computer programs based on at least some user input (para 0025 – CAD software allows manipulation).

Regarding claims 496 and 532, Bradbury discloses dividing at least one image into a plurality of sections (para 0020 – distinguishing the image between hard and soft tissues thus dividing the image into plurality of sections or areas).

7. Claims 156, 157, 495-502, 510, 512-514, 516-517, 519-521, 523-526, 528, 531-546, 548-550, 552-553, 555-557, 559-562 and 564 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duran et al., U.S. Patent No. 6,491,511, further in view of D'Urso U.S. Patent No. 5,741,215 and further in view of Halmann et al., U.S. Patent No. 5,151,856.

Regarding claims 156 and 157, these claims recite two components:

1st component: using first images to create a pattern of at least a portion of at least one patient-specific cardiac instrument or implant using at least one image of heart tissue form a human heart, and

2nd component is using first images to create at least a second image of the heart tissue, wherein at least a portion of the second image appears four-dimensional.

Clearly, there is no connection between these two components except that same first images could be used to perform both components.

Duran discloses "the present invention is in the field of equipment and devices related to manufacturing heart valves to be used in cardiac surgery (col. 1, lines 6-10). Duran further discloses the use of echocardiograms (heart images which includes a heart valve tissues of the heart) data in order to make or construct a custom replacement heart valve (patient specific heart implant/instrument) (col. 6, lines 50-65) but does not expressly provide the details of how such patient specific implant would be created using the heart images data, which details would further include creating a pattern of at least a portion of at least one patient-specific cardiac instrument or implant using at least one image of heart tissue from a human heart. Therefore, examiner cites D'Urso to provide the details of the implant construction.

D'Urso discloses patient specific implant construction which recites the steps of: "obtaining the scan data from an X-ray, MRI, PET scanner and is processed by conventional software to produce, initially, two dimensional boundary images of say, anatomical structure for each tomographic slice. The segmented data is then further processed by conventional contour or voxel methods to produce a three-dimensional data set for the anatomical pathology scanned. The three-

dimensional data may be manipulated by conventional CAD software and this 3D model being the pattern of the at least a portion of the implant which is further used for the construction of the patient specific physical implant (col. 4, lines 14-36; col. 6, lines 29-48). D'Urso further discloses the implants could be for anatomical structures could be hard tissues such as bone (col. 6, lines 31-33) and soft tissues such as aortic junction (arterial and vascular implants) (figure 6; col. 8, lines 45-67). D'Urso does disclose that the patient specific implant could be designed for soft tissues based on tissue images (aortic junction, arterial and vascular implants) (figure 6; col. 8, lines 45-67) and as well known heart is nothing but a structure of soft tissues and as discussed before, D'Urso uses the same method of determining the implant pattern for different kinds of body implants, for example bone and aorta junction. Therefore, it would be obvious to one of ordinary skill in the art at the time of invention was made to combine the teachings of Duran and D'Urso to create a pattern of at least one patient-specific cardiac instrument or implant using at least one image of heart tissue from a human heart because both Duran and D'Urso are directed to the same field of constructing a patient specific body implant and D'Urso provides the details of a method and system which creates a computer model/pattern of the implant according to patient specifics from the tissue images of different parts of the body, thus providing a versatile method and system to provide any kind of computer model/pattern for any kind of human implants, which model would further provide the user with additional manipulation capabilities to improve the geometrical accuracy of the implant, if required, and further adding, such a computer model/pattern could easily be converted into machine instructions to facilitate automated construction of the implant.

As discussed in the rejection with respect to Duran and D'Urso, the images are be used to develop/create multi-dimensional data in order to analyze heart tissues but both Duran and D'Urso do explicitly teach such a multidimensional data to be a 4 dimensional data. As well known 4-

dimensional image is a 3-dimensional image with time dimension added to it so that an animation of 3D image can be provided. It is very well known in the art of medical imaging analysis to create and use 4D images (3D animation) and Halmann teaches the same in (col. 3, lines 50-52; col. 9, lines 15-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to use Halmann's teachings into the combined invention of Duran and D'Urso. One of ordinary skill in the art at the time of invention was made would have been motivated to use Halmann's teachings into the combined invention of Duran and D'Urso because all references are directed to same field of endeavor (medical (heart) analysis) and 4 dimensional images would provide a real time analysis of the heart tissues.

Regarding claims 495 and 531, the combination of Duran and D'Urso discloses the pattern is created automatically by at least one of the computer programs on at least some user input (see D'Urso -col. 6, lines 29-44 – manipulated 3D model generated using CAD software, col. 8, lines 26-30).

Regarding claims 496 and 532, the combination of Duran and D'Urso discloses dividing at least one image into a plurality of sections (D'Urso – col. 7, lines 24-27 - segmenting the scanned image data into different regions of different tissues).

Regarding claims 497 and 533, the combination of Duran and D'Urso discloses the image comprises a plurality of features (Duran – col. 5, lines 1-10, col. 6, lines 50-65- the features being the heart valves with multiple cusps in the image, D'Urso – col. 7, lines 1-15, col. 8, lines 45-67 – the

features being the cranial bone and aortic junction), and wherein at least one of the features comprises a physiological factor (D'Urso – col. 8, lines 45-55 – aortic junction wall thickness reduced or damaged, for example, by atherosclerosis and/or an aneurysm – represents a physiological factor associated with the feature).

Regarding claims 502 and 538, the combination of Duran and D'Urso discloses at least one of the implants comprises a valve (Duran – col. 5, lines 1-10, col. 6, lines 50-65- the heart valves).

Regarding claims 498-501 and 534-537, these claims recite, "wherein at least one of the implants comprises a reinforcing device, wherein the reinforcing device includes a patch; wherein at least one of the implants is a annuloplasty ring; and, one of the implants is a suture ". The combination of Duran and D'Urso as discussed and cited in the rejection of claim 195 discloses that since the same method and system can be used to create a 2d and 3d model/pattern of anatomical structure implant for different kinds of body structures, therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to create a pattern/model of any implant such as a reinforcing device such as a patch, annuloplasty ring and suture, using the same method and system as disclosed by the combination of Duran and D'Urso. The combination of Duran and D'Urso as cited before in the rejection of claim 195 teaches creating the pattern of the cardiac implants using the cardiac images of the implants but does not expressly teach such an implant to be a cardiac reinforcing device. However, the examiner here asserts that cardiac implants such as reinforcing device, annuloplasty ring and suture are very well known cardiac implants (Official Notice Taken). Reinforcing device is used to provide reinforcement of the heart wall during diastolic chamber filling to prevent or reduce cardiac dilation in patients and reinforcing device as a

"patch" provides reinforcement of the heart wall at a localized area, such as a cardiac aneurysm or at an area of the myocardium which has been damaged due to myocardial infarction. Annuloplasty ring is an implant that is used to dictate the shape and contour of the mitral vlave. Suture is a stitch used to hold tissues together. In the previous office action examiner took official notice on the subject matter recited in these claims and applicant does not provide any arguments to traverse the official notice taken, therefore the subject matter recited in these claims is taken to be admitted prior art (see MPEP 2144.04, section C, page 2100-144).

Regarding claims 503-509, 519-520, 539-545 and 555-556, these claims are dependent on claims 156 and 157 and recite patient specific cardiac instruments. Claims 156 and 157 are Markush claims and these claims recite the consideration of either patient specific cardiac instruments or patient specific cardiac implants. Therefore, as per the merits of these independent claims examiner selects patient specific cardiac implants for the purposes of the examination. Claims 503-509, 519-520, 539-545 and 555-556 recite patient specific cardiac instruments and are therefore not selected for the purposes of the examination.

Regarding claims 510 and 546, the combination of Duran and D'Urso discloses extrapolating at least a portion of at least one feature from at least one image of human heart tissue (Duran- col. 6, lines 50-65, Duran discloses extrapolating or estimating the size of the heart valve and its cusps in the echocardiograms; D-Urso – col. 8, lines 44-55- D'Urso discloses using two dimensional scan images estimating a region of the wall thickness in patient's aortic junction to prepare the implant)

Regarding claims 512 and 548, these claims have been similarly analyzed and rejected as per claim 510 and 546, since the feature is in the images (echocardiograms).

Regarding claims 513 and 549, the combination of Duran and D'Urso discloses wherein at least one of the features comprises a numerical feature (Duran- col. 6, lines 50-65 – calculating the size of heart valve and its cusps, where size being the numerical feature).

Regarding claims 514 and 550, these claims recite using two images of the tissue creating at least a portion of three-dimensional image of the tissue. The combination of Duran and D'Urso discloses creating a 3D representation of the tissue using at least two images (D'Urso – col. 4, lines 24-33).

Regarding claims 516, 517, 552 and 553, these claims have been similarly analyzed and rejected as per claims 156-157 and 497.

Regarding claims 521, 523-524 and 557, 559-560, these claims have been similarly analyzed and rejected as per claims 510-513 and 546-549.

Regarding claims 525 and 561, claims 525 and 561 recites "at least one of the computer programs is further executable to assess a volume of at least a portion of the heart tissue". The combination of Duran and D'Urso as disclosed in the rejection of claims 156 and 157, teaches generating a 3-dimensional pattern data of the anatomical structure (heart tissue) from which a physical implant is created. Examiner here asserts that any physical implant that is created inherently

has a volume and therefore, in order to create something that has volume, volume of that thing has to be assessed in the model and is further represented in the 3d model itself in this case as discussed.

Regarding claims 526 and 562, these claims recites "wherein at least one of the computer programs is further executable to compare a contrast between two or more sections in at least one image; and assess a viability of the heart tissue". The combination of Duran and D'Urso as disclosed in the rejection of the claims 156 and 157, disclose that the information from the anatomical images (tissue images) can be used to generate a model/pattern for the patent-specific tissue implant. The combination of Duran and D'Urso further teaches that using the same image information the reason for constructing the implant can also be known i.e. the defective/damaged tissues can be identified for which the implant is needed (D'Urso – col. 4, lines 40-64; col. 8, lines 44-55). Thus the combination of Duran and D'Urso does teach of assessing a viability of the tissues in the images but the combination of Duran and D'Urso does not expressly teach comparing a contrast between two or more sections in at least one image to assess the viability of the tissues in the image. However, examiner here asserts that it is very well known in the medical imaging art to use a contrast to differentiate between different portions of the image (official notice taken) (for example, to detect the damaged tissue portion or abnormality in the tissue – the abnormal part of the tissue would clearly have a different contrast than a normal part of the tissue). Thus contrasting would clearly and remarkably segment the abnormal part of the tissue from the normal part in a natural way and when used in this combined invention of Duran and D'Urso before the implant pattern is generated would make it easier to identify the reason for the implant (defect) and thus, it would have been obvious for one of ordinary skill in the art at the time of invention to use the contrast to differentiate between different sections in the image, to asses viability of the tissue. In the previous office action

examiner took official notice on the subject matter recited in claims 526 and 562 and applicant does not provide any arguments to traverse the official notice taken, therefore the subject matter recited in these claims is taken to be admitted prior art (see MPEP 2144.04, section C, page 2100-144).

Regarding claims 528 and 564, Duran discloses evaluating a curvature of at least a section of a portion of a heart comprising the heart tissue and assessing a shape of at least the portion of heart (col. 6, lines 50-65 – Duran discloses assessing shape for the heart values can be done by determining the size and shape of the valve from the heart valve image and further teaches the curvature (geometry) of such valve can be determined form the shape and dimensions of their mating surfaces (col. 5, lines 50-55)).

8. Claims 518, 527, 529-530, 554, 563 and 565-566 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is an examiner's statement of reasons of allowance: the combination of Duran and D'Urso does not teach the subject matter as recited in these claims.

9. Claims 567-572 are allowed. The reasons of allowance for these claims should be evident from the applicant's arguments as filed in the amendment filed on 04/30/2009.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Examiner note: Examiner has cited particular columns and line numbers in the references as applied to the claims above for the convenience of the applicant. Although the specified citations are representative of the teachings for the art and are applied to the specific limitations within the individual claim, other passages and figures may be applied as well. It is respectfully requested from the applicant in preparing responses, to fully consider the references entirely as potential teachings all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manav Seth whose telephone number is (571) 272-7456. The examiner can normally be reached on Monday to Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali, can be reached on (571) 272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Manav Seth/
Examiner, Art Unit 2624
July 17, 2009